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June 26, 2020

## **VIA E-MAIL**

The Honorable Jeremiah J. McCarthy United States Magistrate Judge United States District Court, Western District of New York 2 Niagara Square Buffalo, New York 14202

RE: Steuben Foods, Inc. v. Jasper Products, LLC, No. 1:13-cv-01118-EAW-JJM

Dear Judge McCarthy,

I write on behalf of Jasper Products to address the term "hot hydrogen peroxide spray" in claim 20 of U.S. Patent No. 6,945,013. As discussed during the June 16, 2020 claim-construction hearing, Jasper agrees with Shibuya and Hood's claim-construction position that the term cannot be construed to avoid indefiniteness. June 6, 2020 Hearing Transcript ("Hg. Tr."), at 28:15–29:4.

A patent must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). While recognizing that "absolute precision is unattainable," this standard nonetheless requires enough precision "to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Id.* at 899 (citation, alteration, and internal quotation omitted). Thus, a claim term is indefinite if its language "might mean several different things and no informed and confident choice is available among the contending definitions." *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (quoting *Nautilus*, 572 U.S. at 911 n.8).

The claims and specification of the '013 patent completely fail to provide a temperature range for "hot hydrogen peroxide spray." Thus, a person of ordinary skill could know the precise temperature of the hydrogen peroxide in question but still not know whether hydrogen peroxide at that temperature meets the "hot" limitation. This defeats the public-notice function that patent claims are required to provide. *See Nautilus*, 572 U.S. at 899.

At the claim-construction hearing, Steuben argued that those skilled in the art would understand "hot" to mean not just "warm" but "really hot," Tr. at 30:6, 30:11–12, 31:13–21 (emphasis added). Obviously, this argument does not clarify the scope of the claim at all—nor does the testimony of Steuben's own expert, Dr. Sharon.

In his deposition, Dr. Sharon confirmed that a person of skill cannot determine the bounds of "hot." While he testified that "hot" has a "threshold" temperature and insisted that a skilled artisan would know what it meant, he could not identify the threshold temperature and testified

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that the art did not teach it:

- Q. Can you tell me what that threshold [temperature] is [cross talk]
- A. I cannot—I will not put precise mathematical number on it. It's a pretty complex matter. If you look in the art, nobody puts a specific number on it. It's understood by a person of ordinary skill in the art what it means to be hot as a sterilant. But I did not put a—and will not put a precise mathematical number on it.

Case 1:10-cv-781, Dkt. 346-3, Sharon Dep., Tr. 27:11-20.

Dr. Sharon further testified that he did not know how one skilled in the art would access the supposed knowledge of the temperature threshold, other than referring to other publications and the patent itself:

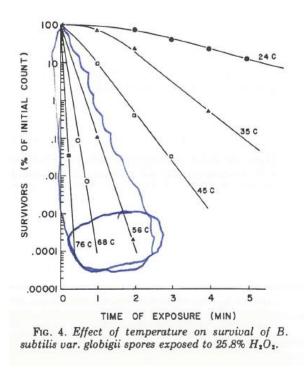
- A. The temperature needs to be considered hot by a person of ordinary skill in the art.
- Q. What I'm trying to get at is, how—how would one access that information if they wanted to stay below the hot range?
- A. I don't know what they would do to stay below the hot range. What they would do to find where you know, what hot is, they would look in publications such as Toledo, and they would look in the patent for any additional guidance, you know, which it gives on the—upper end.

*Id.*. Tr. 54:22–55:10.

But Dr. Sharon could not point to any guidance in the '013 patent. *Id.*, Tr. 56:1–4. And when presented with the publication he referenced, the Toledo paper, he could not identify any minimum threshold temperature: "Toledo does not put a precise mathematical number. Toledo gives you a range of curves." *Id.*, Tr. 57:5–7.

Figure 4 from the Toledo paper plots the survival rate of a particular type of bacteria over time when exposed to a specified concentration of hydrogen peroxide at various temperatures. When shown the range of time-and-temperature curves in this figure, Dr. Sharon circled three curves that he considered "hot"—the 76°C, 68°C, and 56°C curves:

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*Id.*, Tr. 63:5–7 & Ex. 3. But Dr. Sharon refused to say whether the 45°C or 35°C curves would be considered "hot":

- Q. Can you tell me whether the 35 degree or 45 degree would be considered hot?
- A. I'm not—I'm not going to give—I'm not going to give a precise number like that. I mean, you know, I think it's pretty clear in looking at this, what would be considered hot.

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- Q. Are you able to tell me for the other three curves [45°C, 35°C, and 24°C] whether or not a skilled artisan would consider them to be hot with reasonable certainty?
- A. What I can tell you is that I think a skilled artisan would not consider 24 degrees C to be hot and—as far as, you know, now you're wanting to put a precise mathematical number on that, you know, for hot you know, I'm not going to do [it].

## *Id.*, Tr. 61:5–12, 63:9–19 (objections omitted).

Thus, according to Steuben's own expert, the minimum threshold for "hot" is between 56°C and 24°C—*i.e.*, 132°F and 75°F. Locating the low end of "hot" somewhere between a beautiful spring day and the hottest temperature ever recorded on Earth does not provide clear notice of what is claimed. *See Nautilus*, 572 U.S. at 899. And even as to that broad range of "hot"

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temperatures, Dr. Sharon equivocated. Although he testified that he would not consider 24°C hydrogen peroxide to be "hot," he agreed that the Toledo paper shows hydrogen peroxide to be an effective anti-microbial agent at that temperature if exposed to the microbes at the right concentration and for the right length of time. Case 1:10-cv-781, Dkt. 346-3, Tr. 15:15–16:6; *see also* Fig. 4 above. Dr. Sharon also testified that a skilled artisan would consider 50°C hydrogen peroxide "hot" even if were ineffective, such as at a very low concentration. *Id.*, Tr. 47:21–49:12.

Steuben's proposed construction—hot enough to be effective but not so hot as to deform the bottles—calls Dr. Sharon's broad, imprecise temperature range even further into question. If the bounds of "hot" hydrogen peroxide are tied to its effectiveness as a sterilant, hydrogen peroxide heated to a particular temperature may be effective at a particular concentration for a particular length of time but ineffective at a different concentration for a different length of time. In Geneva Pharmaceuticals, Inc. v. GlaxoSmithKlinePLC, 349 F.3d 1373 (Fed. Cir. 2003), the Federal Circuit refused to adopt a proposed construction for the claim term "synergistically effective amount" that would exclude "a given antibiotic, bacteria, or disease combination [that] provides no synergy." Id. at 1384. The court found that under this proposed construction, a particular formulation "might infringe or not depending on its usage in changing circumstances," which is "the epitome of indefiniteness." Id. (affirming summary judgment of invalidity); see also Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1255 (Fed. Cir. 2008) ("When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite."). Steuben's proposed "hot enough to be effective" construction would create exactly that improper outcome—i.e., "hot" hydrogen peroxide sprays that would sometimes infringe and sometimes not, depending on concentration and time of exposure. Because changing the concentration and length of exposure makes hydrogen peroxide either effective or ineffective as an anti-microbial agent at a particular temperature, no skilled artisan applying Steuben's proposed construction could make an "informed and confident choice" when attempting to determine the lower limit of "hot." See Media Rights, 800 F.3d at 1371.

The upper boundary of "hot" is also indefinite under Steuben's proposed construction, because the meaning of "hot" would change with the type of packaging material being used. *See* '013 patent, 15:56–64 (comparing claim 4 (using glass bottles) with claim 5 (using plastic bottles)). It is also unclear whether the supposed upper boundary of "hot" limits the scope of the terms. Dr. Sharon testified that the temperature of bottle deformation simply defined the "window of operation," not the claim term. Case 1:10-cv-781, Dkt. 346-3, Tr. 53:14–54:3.

The additional authority Steuben cited at the claim-construction hearing provides no further clarity. See Hg. Tr. at 27:11–14. Exmark Manufacturing Co. v. Briggs & Stratton Power Products Group, 879 F.3d 1332 (Fed. Cir. 2018), stands only for the Federal Circuit's previously articulated proposition that functional language can "promote[] definiteness because it helps bound the scope of the claims by specifying the operations that the [claimed invention] must undertake." Id. at 1346 (quoting Cox Commc'ns, Inc. v. Sprint Commc'n Co., 838 F.3d 1224, 1232 (Fed. Cir. 2016)). But the claims and specification of the '013 patent do not provide the type of functional language that helped define the bounds of the asserted claims in Exmark, which recited a multiblade lawn-mower deck with "elongated and substantially straight baffle portions" oriented so that "the cuttings from

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said first cutting blade will be deflected inwardly within the said circle defined by the blade tip path of said second cutting blade." *Id.* By observing whether the baffle portions deflected cuttings as claimed and comparing them to other components of the baffle and mower to determine whether they were, in fact, "elongated and substantially straight," a skilled artisan "would understand the objective boundaries of the claim." *Id.* at 1347.

Here, the only functional language Steuben identifies is related to the hydrogen peroxide's effectiveness as an anti-microbial agent. As shown above, even hydrogen peroxide at temperatures that Dr. Sharon would not identify as "hot" during his deposition can be effective at achieving commercial sterility depending on the concentration and time of exposure. Thus, unlike the detailed functional language of the *Exmark* claims, the spare and limited functional language of the claims and specification at issue in this case does not permit a skilled artisan to define "hot" with reasonable certainty.

Because nothing in the patent or the art teaches the boundaries of "hot" hydrogen peroxide with reasonable certainty, the term is indefinite and incapable of construction.

Sincerely,

HOVEY WILLIAMS LLP

Michael B. Hurd

cc: All counsel of record (via ECF)